

TO: **Mail Stop 8**
Director of the U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

**REPORT ON THE
 FILING OR DETERMINATION OF AN
 ACTION REGARDING A PATENT OR
 TRADEMARK**

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been
 filed in the U.S. District Court _____ Eastern District of New York _____ on the following

☒ Trademarks or ☒ Patents. (☐ the patent action involves 35 U.S.C. § 292.);

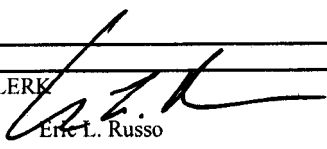
| | | |
|------------------------------------|--------------------------------|--|
| DOCKET NO. 11-CV-1280 | DATE FILED March 17, 2011 | U.S. DISTRICT COURT Eastern District of New York |
| PLAINTIFF Glycobioscience, Inc. | | DEFENDANT Nycomed US, Inc., Pharmaderm and Jagotec AG |
| PATENT OR TRADEMARK NO. | DATE OF PATENT OR TRADEMARK | HOLDER OF PATENT OR TRADEMARK |
| 1 5,897,880 | | SEE ATTACHED COMPLAINT FOR DETAILS |
| 2 6,723,345 | | |
| 3 5,639,738 | | |
| 4 5,792,753 | | |
| 5 5,852,002 | | |

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

| | | | |
|----------------------------|---|------------------------------------|--|
| DATE INCLUDED | INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading | | |
| PATENT OR TRADEMARK NO. | DATE OF PATENT OR TRADEMARK | HOLDER OF PATENT OR TRADEMARK | |
| 1 5,914,322 | | SEE ATTACHED COMPLAINT FOR DETAILS | |
| 2 5,929,048 | | | |
| 3 5,985,850 | | | |
| 4 | | | |
| 5 | | | |

In the above—entitled case, the following decision has been rendered or judgement issued:

| |
|--------------------|
| DECISION/JUDGEMENT |
|--------------------|

| | | |
|------------------------------|--|-------------------|
| CLERK ROBERT C. HEINEMANN | (BY) DEPUTY CLERK  Eric L. Russo | DATE 3/17/2011 |
|------------------------------|--|-------------------|

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
 Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

infringe the claims of the '880 patent by licensing the manufacture, distribution, use and/or sale of the FDA approved drug product called SOLARAZE® Gel within the United States.

41. SOLARAZE® Gel pharmaceutical products include the formulation as taught and claimed in the '880 patent in suit and is covered by Claims 1 and 7 of the '880 patent as described above.

42. Jagotec's infringement is a literal infringement and/or an equivalent infringement of the claims and is direct, contributory and inducing.

43. Plaintiff is entitled to recover from the Defendant Jagotec the damages sustained, reasonable royalty, lost profits of Plaintiff and/or profits of Defendants as a result of Defendant's infringing acts.

44. Defendant Jagotec has had knowledge of Plaintiff's rights in the '880 patent and has continued infringement with full knowledge of and in disregard for those rights, such actions constituting willful infringement.

PATENT INFRINGEMENT OF US 6,723,345

45. Plaintiff realleges each and every allegation set forth above and incorporates them herein by reference.

46. Plaintiff owns and has at all relevant times owned, has acquired from Lam Pharmaceuticals by assignment and acquisition and has and has had standing to sue for infringement of United States Letters Patent 6,723,345.

47. The '345 patent properly names as inventors Alen Drizen, Peter Rothbart and Gary Nath and was properly assigned to Lam Pharmaceuticals.

COUNT IV
PATENT INFRINGEMENT BY NYCOMED

48. Plaintiff realleges each and every allegation set forth above and incorporates them herein by reference.

49. Upon information and belief, Defendant Nycomed has infringed and continues to infringe claims 1, 3, 5 and 8 of the '345 patent.

50. Upon information and belief, Defendant Nycomed has infringed and continues to infringe the claims of the '345 patent by manufacturing or causing to be manufactured, distributing, using, offering to sell, and/or selling, through its wholly owned subsidiary PharmaDerm, the FDA approved drug product called SOLARAZE® Gel within the United States.

51. SOLARAZE® Gel pharmaceutical products include the formulation as taught and claimed in the '345 patent in suit and is covered by Claims 1, 3, 5 and 8 of the '345 patent as described above.

52. Nycomed's infringement is a literal infringement and/or an equivalent infringement of the claims and is direct, contributory and inducing.

53. Plaintiff is entitled to recover from the Defendant Nycomed the damages sustained, reasonable royalty, lost profits of Plaintiff and/or profits of Defendants as a result of Defendant's infringing acts.

54. Defendant Nycomed has had knowledge of Plaintiff's rights in the '345 patent and has continued infringement with full knowledge of and in disregard for those rights, such actions constituting willful infringement.

COUNT V
PATENT INFRINGEMENT BY PHARMADERM

55. Plaintiff realleges each and every allegation set forth above and incorporates them herein by reference.

56. Upon information and belief, Defendant PharmaDerm has infringed and continues to infringe claims 1, 3, 5 and 8 of the '345 patent.

57. Upon information and belief, Defendant PharmaDerm has infringed and continues to infringe the claims of the '345 patent by manufacturing or causing to be manufactured, distributing, using, offering to sell, and/or selling the FDA approved drug product called SOLARAZE® Gel within the United States.

58. SOLARAZE® Gel pharmaceutical products include the formulation as taught and claimed in the '880 patent in suit and is covered by Claims 1 and 7 of the '880 patent as described above.

59. PharmaDerm's infringement is a literal infringement and/or an equivalent infringement of the claims and is direct, contributory and inducing.

60. Plaintiff is entitled to recover from the Defendant PharmaDerm the damages sustained, reasonable royalty, lost profits of Plaintiff and/or profits of Defendants as a result of Defendant's infringing acts.

61. Defendant PharmaDerm has had knowledge of Plaintiff's rights in the '345 patent and has continued infringement with full knowledge of and in disregard for those rights, such actions constituting willful infringement.

COUNT VI
PATENT INFRINGEMENT BY JAGOTEC

62. Plaintiff realleges each and every allegation set forth above and incorporates them herein by reference.

63. Upon information and belief, Defendant Jagotec has infringed and continues to infringe claims 1, 3, 5 and 8 of the '345 patent.

64. Upon information and belief, Defendant Jagotec has infringed and continues to infringe the claims of the '345 patent by licensing the manufacture, distribution, use and/or sale of the FDA approved drug product called SOLARAZE® Gel within the United States.

65. SOLARAZE® Gel pharmaceutical products include the formulation as taught and claimed in the '345 patent in suit and is covered by Claims 1, 3, 5 and 8 of the '345 patent as described above.

66. Jagotec's infringement is a literal infringement and/or an equivalent infringement of the claims and is direct, contributory and inducing.

67. Plaintiff is entitled to recover from the Defendant Jagotec the damages sustained, reasonable royalty, lost profits of Plaintiff and/or profits of Defendants as a result of Defendant's infringing acts.

68. Defendant Jagotec has had knowledge of Plaintiff's rights in the '345 patent and has continued infringement with full knowledge of and in disregard for those rights, such actions constituting willful infringement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgement against Defendants as follows:

69. That Defendants be each individually held to have infringed the claims of the '880 and '345 patents in suit.

70. That the Defendants be held to have willfully infringed the patents in suit.

71. That Defendants, their customers, licensees, directors, officers, agents, servants, employees and all other persons in active concert or privity or in participation with them be enjoined from directly or indirectly infringing Plaintiff's patents.

72. That Defendants each individually be enjoined to deliver upon oath, to be impounded during the pendency of this action, and delivered to Plaintiff pursuant to judgement herein, all originals, copies, facsimiles, or duplicates of any device shown by the evidence to infringe Plaintiff's patents.

73. That judgement be awarded to Plaintiff under 35 U.S.C. §§271, 281, 284 and/or 285.

74. That judgement be entered for Plaintiff against Defendants, for Plaintiff's actual damages according to proof, for reasonable royalties and for any profits attributable to infringements of Plaintiff's patents.

75. That judgement be entered for Plaintiff against Defendants, for statutory damages based upon Defendants' acts of patent infringement and for its other violations of law.

76. That Defendants be required to account for all gains, profits, and advantages derived from its acts of infringement and for its other violations of law.

77. That judgement be entered for Plaintiff and against Defendants, for trebling of the damages awarded for patent infringement due to willful infringement.

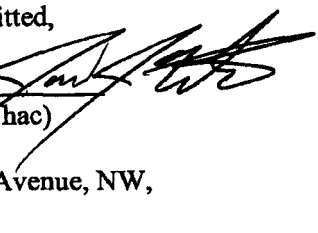
78. That Plaintiff have judgement against the Defendants for Plaintiff's costs and attorney's fees.

79. That the Court grant such other, further, and different relief as the Court deems proper under the circumstances.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests and demands a trial by jury on all issues so triable.

Respectfully submitted,


/s/ Joseph J. Zito
Joseph J. Zito (pro hac)
ZITO tlp
1250 Connecticut Avenue, NW,
Suite 200
Washington, D.C. 20036
Tel: (202) 466-3500
E-mail: jzito@zitotlp.com

Attorneys for Plaintiff



**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

CV-11 1280

GLYCOBIOSCIENCES, Inc.
7 Timber Court
Georgetown, Ontario
L7G 4S4 Ontario, Canada

Plaintiff

v.

NYCOMED US, Inc.
60 Baylis Road
Melville, New York 11747-0103

PHARMADERM
210 Park Avenue
Fordham Park, New Jersey 07932

and

JAGOTEC AG
Eptingerstrasse 51
CH-4132 Muttenz, Switzerland

Defendants

(S.F.)

FILED
IN CLERK'S OFFICE
U.S. DISTRICT COURT E.D.N.Y.

Civil Action No.

★ MAR 17 2011 ★

LONG ISLAND OFFICE

SEYBERT, J.
WALL, M.J.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, GlycoBioSciences, Inc., by counsel, for its complaint against Defendants,
Nycomed US, Inc., Pharmaderm and Jagotec AG, states as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement under 35 U.S.C. § 271.
2. This Court has jurisdiction of this action under 28 U.S.C. §§ 1331, 1338(a).
3. Plaintiff, GlycoBioSciences, is a corporation existing under the laws of Canada

located at 7 Timber Court, Georgetown, Ontario, L7G 4S4, Ontario Canada, is the developer of a product for relief of Arthritic pain, referred to as IPM Diclofenac Pain Gel and is the owner of United States Letters Patent 5,897,880 (the '880 patent) and 6,723,345 (the '345 patent) both entitled Topical Drug Preparations.

4. Defendant Nycomed US, Inc, upon information and belief, is a corporation organized and existing under the laws of the State of New York and has a principle place of business at: 60 Baylis Road, Melville, New York 11747-0103 and is the owner of NDA No. 21-005 and the FDA approved drug product called SOLARAZE® Gel. Nycomed is engaged in making, importing, using, offering for sale and/or selling the SOLARAZE® Gel pharmaceutical products which include the formulation as taught and claimed in the '880 and '345 patents in suit and is covered by Claims of the '880 and '345 patent. The products, which are covered under the claims of the '880 and '345 patents in suit, are being sold throughout the United States, including substantial sales in New York and in the Judicial District of the Eastern District of New York. Jurisdiction and Venue are proper in this District as to Defendant Nycomed, under 28 U.S.C. §1391(b), and §1400(b).

5. Defendant PharmaDerm is a wholly owned subsidiary of Nycomed US Inc. and has a principle place of business at 210 Park Avenue, Florham Park, New Jersey 07932. PharmaDerm markets and sells SOLARAZE® Gel which includes the formulation as taught and claimed in the '880 and '345 patents in suit and is covered by Claims of the '880 and '345 patents. The products, which are covered under the claims of the '880 and '345 patents in suit, are being sold throughout the United States, including substantial sales in New York and in the Judicial District of the Eastern District of New York. Jurisdiction and Venue are proper in this District as to Defendant PharmaDerm, under 28 U.S.C. §1391(b), and §1400(b).

6. Defendant Jagotec AG, upon information and belief, is a company existing under Swiss law having a principle place of business at: 51, CH-4132 MuttENZ, Switzerland. Jagotec is the owner and licensor of patents 5,639,738; 5,792,753; 5,852,002; 5,914,322; 5,929,048; and 5,985,850 (the Solaraze patents). The Solaraze patents are listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* on connection with NDA No. 21-005 and the SOLARAZE® Gel pharmaceutical products. Upon information and belief, the Solaraze patents are exclusively licensed by Jagotec to Nycomed for its production and sales of SOLARAZE® Gel. Upon information and belief, Jagotec receives income from the sale of SOLARAZE® Gel pharmaceutical products by Defendants Nycomed and PharmaDerm. The products, which are covered under the claims of the '880 and '345 patents in suit, are being sold throughout the United States, including substantial sales in New York and in the Judicial District of the Eastern District of New York. Jurisdiction and Venue are proper in this District as to Defendant Jagotec, under 28 U.S.C. §1391(d), and §1400(b).

GENERAL ALLEGATIONS

7. Plaintiff is a research pharmaceutical company which has developed IPM Diclofenac Pain Gel for Arthritic Pain and a wound healing gel as well as other formulations for the treatment of dermatological conditions and other indications.

8. Plaintiff has invested significant resources in the development of IPM Diclofenac Pain Gel, has applied for FDA approval for use as an arthritic treatment and is preparing to introduce the product into the market in the near future.

9. Defendants manufacture, offer for sale and sell SOLARAZE® Gel which is advertised and approved for the treatment of dermatological conditions known as actinic keratosis (AK). PharmaDerm describes actinic keratosis in its SOLARAZE® Gel literature: "AK

is a chronic skin condition".

10. The SOLARAZE® Gel product literature and FDA product information sheet describes SOLARAZE® Gel as:

SOLARAZE® Gel is a nonsteroidal anti-inflammatory therapy that is FDA approved for the topical treatment of AK lesions.

SOLARAZE® Gel contains the active ingredient diclofenac sodium, which is a type of medicine called a non-steroidal anti-inflammatory drug (NSAID). These drugs are commonly used in many areas of medicine. NSAIDs are known to provide both anti-inflammatory and anti-neoplastic (anti-cancer) benefits.

Solaraze® Gel contains diclofenac sodium, benzyl alcohol, hyaluronate sodium, polyethylene glycol monomethyl ether, and purified water.

11. United States Patent 5,897,880, entitled Topical Drug Preparations, issued on April 27, 1999 from a patent application with a filing priority date of September 29, 1995.

12. The '880 patent was issued after careful examination by the United States Patent and Trademark Office, which determined the invention as claimed to be new, useful and unobvious.

13. The '880 patent grants protection to Plaintiff's claimed formulation for a Topical Drug Preparation and includes claims 1 and 7 which describes the protected invention:

1. A stable, sterile gelled composition which comprises: a matrix containing a negative charged polymer consisting of sodium hyaluronate blended with a nonionic polymer, wherein the molar ratio of the negative charged polymer to the nonionic polymer is 1:0.5 to 4 and the negative charged polymer is present in amounts of about 2.0% to about 3.5% by weight of the resulting composition, and wherein the composition is storage stable and is capable of being topically administered to an animal.

7. An antiarthritic gelled composition, which comprises: therapeutically effective amounts of an active NSAID drug dispersed within a matrix containing a negative charged polymer consisting of sodium hyaluronate blended with a nonionic polymer, wherein the molar ratio of the charged polymer to the nonionic polymer is 1:0.5 to 4 and the negative charged polymer is present in amounts of about 2.0% to about 3.0% by weight of the resulting composition, and wherein the composition is storage stable and transdermally delivers said therapeutically effective amounts of the

NSAID drug.

14. United States Patent 6,723,345, entitled Topical Drug Preparations, issued on April 20, 2004 from a patent application with a filing priority date of September 29, 1995.

15. The '345 patent was issued after careful examination by the United States Patent and Trademark Office, which determined the invention as claimed to be new, useful and unobvious.

16. The '345 patent grants protection to Plaintiff's claimed formulation for a Topical Drug Preparation and includes claims 1, 3, 5 and 8, which describe the protected invention:

1. A method for treating a dermatologic condition in an animal, which comprises: topically applying to said animal a therapeutically effective dose of a gelled composition for treating said dermatologic condition comprising a polymer matrix which is suspended in a liquid medium;

wherein the polymer matrix contains sodium hyaluronate in combination with a nonionic polymer.

3. The method of claims 1, wherein said condition is dermatitis.

5. A method for treating a dermatologic condition in an animal, which comprises: topically applying to said animal a gelled composition comprising a therapeutically effective dose of a drug for treating the dermatologic condition uniformly distributed in a polymer matrix which is suspended in a liquid medium;

wherein the polymer matrix contains sodium hyaluronate in combination with a nonionic polymer.

8. The method of claim 5, wherein said dermatologic condition is dermatitis.

17. SOLARAZE® Gel is a stable, sterile gelled composition which comprises: a matrix containing a negative charged polymer consisting of sodium hyaluronate blended with a nonionic polymer (polyethylene glycol monomethyl ether), wherein the molar ratio of the negative charged polymer to the nonionic polymer is 1:0.5 to 4 and the negative charged polymer (hyaluronate sodium) is present in amounts of 2.5% by weight of the resulting

composition, and wherein the composition is storage stable and is capable of being topically administered to an animal.

18. The active ingredient diclofenac sodium used in SOLARAZE® Gel is a known active NSAID drug.

19. SOLARAZE® Gel is used as method for treating a dermatologic condition in an animal, by topically applying to said animal a therapeutically effective dose of a gelled composition for treating said dermatologic condition comprising a polymer matrix which is suspended in a liquid medium; wherein the polymer matrix contains sodium hyaluronate in combination with a nonionic polymer (polyethylene glycol monomethyl ether).

20. Actinic keratosis, the condition treated by SOLARAZE® Gel, is a chronic skin condition i.e. a form of dermatitis.

PATENT INFRINGEMENT OF US 5,897,880

21. Plaintiff realleges each and every allegation set forth above and incorporates them herein by reference.

22. Plaintiff owns and has at all relevant times owned, has acquired from Lam Pharmaceuticals by assignment and acquisition and has and has had standing to sue for infringement of United States Letters Patent 5,897,880.

23. The '880 patent properly names as inventors Alen Drizen, Peter Rothbart and Gary Nath and was properly assigned to Lam Pharmaceuticals.

COUNT I
PATENT INFRINGEMENT BY NYCOMED

24. Plaintiff realleges each and every allegation set forth above and incorporates them herein by reference.

25. Upon information and belief, Defendant Nycomed has infringed and continues to infringe claims 1 and 7 of the '880 patent.

26. Upon information and belief, Defendant Nycomed has infringed and continues to infringe the claims of the '880 patent by manufacturing or causing to be manufactured, distributing, using, offering to sell, and/or selling, through its wholly owned subsidiary PharmaDerm, the FDA approved drug product called SOLARAZE® Gel within the United States.

27. SOLARAZE® Gel pharmaceutical products include the formulation as taught and claimed in the '880 patent in suit and is covered by Claims 1 and 7 of the '880 patent as described above.

28. Nycomed's infringement is a literal infringement and/or an equivalent infringement of the claims and is direct, contributory and inducing.

29. Plaintiff is entitled to recover from the Defendant Nycomed the damages sustained, reasonable royalty, lost profits of Plaintiff and/or profits of Defendants as a result of Defendant's infringing acts.

30. Defendant Nycomed has had knowledge of Plaintiff's rights in the '880 patent and has continued infringement with full knowledge of and in disregard for those rights, such actions constituting willful infringement.

COUNT II
PATENT INFRINGEMENT BY PHARMADERM

31. Plaintiff realleges each and every allegation set forth above and incorporates them herein by reference.

32. Upon information and belief, Defendant PharmaDerm has infringed and continues

to infringe claims 1 and 7 of the '880 patent.

33. Upon information and belief, Defendant PharmaDerm has infringed and continues to infringe the claims of the '880 patent by manufacturing or causing to be manufactured, distributing, using, offering to sell, and/or selling the FDA approved drug product called SOLARAZE® Gel within the United States.

34. SOLARAZE® Gel pharmaceutical products include the formulation as taught and claimed in the '880 patent in suit and is covered by Claims 1 and 7 of the '880 patent as described above.

35. PharmaDerm's infringement is a literal infringement and/or an equivalent infringement of the claims and is direct, contributory and inducing.

36. Plaintiff is entitled to recover from the Defendant PharmaDerm the damages sustained, reasonable royalty, lost profits of Plaintiff and/or profits of Defendants as a result of Defendant's infringing acts.

37. Defendant PharmaDerm has had knowledge of Plaintiff's rights in the '880 patent and has continued infringement with full knowledge of and in disregard for those rights, such actions constituting willful infringement.

COUNT III
PATENT INFRINGEMENT BY JAGOTEC

38. Plaintiff realleges each and every allegation set forth above and incorporates them herein by reference.

39. Upon information and belief, Defendant Jagotec has infringed and continues to infringe claims 1 and 7 of the '880 patent.

40. Upon information and belief, Defendant Jagotec has infringed and continues to